

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 1

1 Congress Street, Suite 1100 BOSTON, MA 02114-2023

#### **CERTIFIED MAIL**

FILE COPY

January 25, 2005

Michael A. Teague, Ph.D. Vice President / ESHA Clariant Corporation 4000 Monroe Road Charlotte, North Carolina 28205

Re:

Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, December 6, 2004

Dear Dr. Teague:

This is in response to your December 6, 2004 Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214. EPA's contractor, Versar, has completed its review of this submittal. Versar's comments are attached.

EPA expects Clariant to make any necessary revisions to the comprehensive assessments as soon as possible. Accordingly, EPA requests that Clariant provide its estimated schedule for completion of the revised assessments within 7 days of receipt of this letter.

Should you have any questions, please call me at (617) 918-1527 or by e-mail at tisa.kimberly@epa.gov.

Sincerely,

Kimberly N. Tisa, PCB Coordinator

Office of Ecosystem Protection

CC:

T. Olivier, EPA M. Milette, EPA

attachment



#### MEMORANDUM

TO:

Laura Casey

cc:

Jim Buchert

11.1126.1000.001.01

FROM:

Diane Sinkowski

DATE:

January 23, 2005

SUBJECT:

Review of "Exposure and Screening-level Risk Assessment for Carpet Fiber and

Food Wrap Scenarios Associated with Pigment Red 144/214" (December 6, 2004)

I have the reviewed the submitted risk assessment and have provided, below, comments addressing the items specified by EPA in the technical direction provided by Region I on 12/20/04.

1. Does the *Exposure Assessment* consider all pathways for the uses included in the assessment? If not, please provide comments and/or recommendations. Please include Versar's justifications using appropriate EPA procedures and guidance.

The pathways considered seem appropriate for the exposure scenarios evaluated.

2. Were Versar's October 25, 2004 comments adequately addressed in the *Exposure Assessment?* If not, please provide comments and/or recommendations. Please include Versar's justifications using appropriate EPA procedures and guidance.

Versar's previous comments have been adequately addressed.

- 3. Are there areas where data gaps exist and where additional information is required? Versar shall identify any data deficiencies, and if found, provide possible resolutions such as (but not limited to) the collection of additional samples or requesting additional information.
- On page 2-5, the risk assessment indicates that a soil dust ingestion rate of 55 mg per day
  was assumed for children and is based on data from Moya et al. (2004). I was unable to
  find this value in the cited reference. The Moya et al. reference states the following:

Children's mean soil ingestion values ranged from 39 mg/day to 271 mg/day with an average of 138 mg/day for soil ingestion and 193 mg/day for soil and dust ingestion. Upper percentile values average 358 mg/day for soil and 790 mg/day for soil and dust combined.

Could Clariant please provide clarification on the origin of the assumed value?

- Clariant should provide information regarding exposure frequency and duration for the food wrap scenario and revise the calculations shown at the bottom of page 3-2 accordingly, since the calculations only reflect one day's consumption of cheese. In particular, for carcinogenic risk, the calculated daily dose shown, 0.0000014 mg tPCBs/kg BW/day, cannot be compared to the target lifetime average daily dose of 0.000014 mg/kg BW/day (Table 1) without dividing by the lifetime averaging time (i.e., 25,550 days).
- Table 1 (page 7-1) of the risk assessment indicates that a slope factor of 0.07 (mg/kg-d)<sup>-1</sup> was assumed for calculating the cancer risk from ingestion, dermal absorption, and inhalation of PCBs. The value is the upper-bound slope factor for PCBs of the lowest risk and persistence. EPA's criteria for use of this slope factor (www.epa.gov/iris/subst/0294.htm) is that congener or isomer analyses verify that congeners with more than 4 chlorines comprise less than 1/2% (0.5%) of total PCBs. Page 1-2 (bottom paragraph) of the risk assessment indicates that PCB congeners 44 and 70 make up approximately 90 percent of the total PCBs found in Pigment Red 144 and 214. It is uncertain from this statement whether the additional PCB congeners in the pigments are of low chlorine content. Clariant should demonstrate to EPA that the composition of the pigments meets EPA's criteria for use of the 0.07 (mg/kg-d)<sup>-1</sup> slope factor.
- 4. Are the formulas provided in the *Exposure Assessment* appropriate and are the proposed exposure/risk model input parameters correct? If not, please provide comments and/or recommendations using appropriate EPA procedures and guidance.
- According to the risk assessment, Equation 4 (page 2-3) is obtained by substituting
  Equation 3 into Equation 2 (both on page 2-2), and solving for C<sub>g</sub> (room air concentration
  of tPCB vapor). Equation 4 (without the parameter "D") is as follows:

$$C_{g} = \left(\frac{d_{w} \times 10^{3.83 \cdot 0.62 \times \log VP}}{M}\right)$$

However, as shown in the steps below, the substitution has not been performed correctly:

Given: 
$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82-0.62 \times logVP}$$

and

$$K_{eq} = \frac{k_s}{k_d} = \frac{M}{C_g}$$

Substituting for  $\frac{k_s^2}{k_d}$ :

$$K_{SA} = \frac{\frac{M}{C_g}}{d_w} = 10^{3.82 \cdot 0.62 \times logVP}$$

Rearranging to solve for C<sub>g</sub>:

$$C_{g} = \frac{\frac{M}{10^{3.82 \cdot 0.62 \times \log VP}}}{d_{w}} = \frac{M}{d_{w} \times 10^{3.82 \cdot 0.62 \times \log VP}}$$

This correction should be made and any calculations performed using this equation should be revised.

- The parameter M, as defined in the risk assessment, is incorrect. Table 1 (page 7-1) of the risk assessment indicates that M is the carpet area mass (face weight; mg/m²). The parameter M, as defined in the Bennett and Furtaw (2004) and the Won, et al. (2000) papers, is the mass of the compound [PCBs] collected on the sink [carpeting] per unit area (mg/m²). Therefore, the value shown in Table 1 for the carpet area mass and the calculated air concentration in an enclosed space 7 days post installation of a new carpet are incorrect, unless Clariant means to assume that the entire mass of the carpet is tPCBs.
- Equation 5 from the risk assessment (see below), has parameters representing the tPCB concentration in the carpeting (CC<sub>Carpet</sub>) and the concentration in the air (C<sub>g</sub>). There cannot be two concentration parameters in the equation. When a unit analysis is done, one can see that the ingestion and dermal absorption parameters cancel to mg/kg as they should, since the equation is being solved for CC<sub>Carpet</sub> which is in units of mg/kg. However, when the units for the inhalation contribution to the equation are canceled, the term is unitless instead of being mg/kg. Equation 5 and the calculations for CC<sub>Carpet</sub> should be revised.

$$CC_{copel} = \frac{TR \times BW \times AT_{o}}{ED \times EF \times \left[ \left( \frac{CSF \times IR \times BioAF}{10^{6} \text{ mg/kg}} \right) + \left( \frac{CSF \times SA \times AF \times DERM}{10^{6} \text{ mg/kg}} \right) + \left( \frac{CSF \times IHR \times C_{g} \times VRF}{10^{6} \text{ mg/kg}} \right) \right]}$$

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$$CC_{\text{expet}} \text{ (inhalation term only)} \left( \frac{mg}{kg} \right) = \frac{TR \times BW \times AT_{e}}{ED \times EF \times \left( CSF \times IHR \times C_{g} \times VRF \right)} = \frac{(-) \times (kg) \times (days)}{(yr) \times \left( \frac{days}{yr} \right) \times \left( \frac{mg}{kg - day} \right)^{-1} \times \left( \frac{m^{2}}{day} \right) \times \left( \frac{mg}{m^{2}} \right) \times \left( -\right)} = (-)$$

- A volatilization rate factor, VRF, is included in the inhalation exposure calculation. However, since the equation from the Bennett and Furtaw (2004) paper, already takes into account desorption of the compound (tPCBs) from the sink material (carpeting), a VRF should not be included in the calculation if the methodology from the Bennet and Furtaw paper is to be used to calculate a tPCB air concentration.
- A bioavailability factor, (assumed values were 1, 5, 10, 50, and 100%, see Table 1), was included in the calculation of the ingestion dose. Although EPA has studied and provided some guidance regarding the relative bioavailability of metals, such as lead, at this time, U.S. EPA has not provided guidance for PCBs. Until EPA reviews all the studies on PCBs and comes to a consensus regarding the relative bioavailability of PCBs in soil, no bioavailability factors should be included when calculating PCB intakes via the ingestion pathway.

Please contact me if there are any questions regarding these comments or if additional information is needed.



To: Kimberly Tisa/R1/USEPA/US@EPA

CC:

Subject: Fw: Clariant Carpet Fiber and Food Wrap RA

#### Good Morning

Here you go. Are you dug out yet?

Laura

---- Forwarded by Laura Casey/DC/USEPA/US on 01/25/05 07:17 AM ----



Diane Sinkowski <DSinkowski@versar.com> 01/24/05 11:46 AM

To Laura Casey/DC/USEPA/US@EPA

cc James Buchert < BUCHEJAM@versar.com>

Subject Clariant Carpet Fiber and Food Wrap RA

Hi Laura,

Please find attached comments on the risk assessment performed by Clariant (Dec. 6, 2004) on exposure to carpet fiber and food wrap. I'd be happy to answer any questions you or Kim may have.

Thank you,

Didi

Diane S. Sinkowski
Environmental Engineer
Exposure/Risk Assessment Division
Versar, Inc.
6850 Versar Center
Springfield, VA 22151
Phone: 703-750-3000, ext. 737
Fax: 703-642-6954
dsinkowski@versar.com



clarient carpet fiber and food wrap.wpd



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 Congress Street, Suite 1100 BOSTON, MA 02114-2023



#### **CERTIFIED MAIL**

January 25, 2005

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Please contact me if there are any questions regarding these comments or if additional information is needed.

Furtaw paper is to be used to calculate a tPCB air concentration.



**Clariant Corporation** 

4000 Monroe Road Charlotte, NC 28205 704.331.7000

Via FedEx

December 6, 2004

Kimberly Tisa, PCB Coordinator (CPT) U.S. Environmental Protection Agency 1 Congress Street, Suite 1100 Boston, MA 02114-2023

RE: Red Pigment Project

**Exposure and Screening-Level Risk Assessments** 

Dear Ms. Tisa:

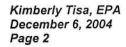
Per Clariant's November 8, 2004 correspondence, please find enclosed the document titled "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214" prepared for Clariant by BBL Sciences.

The risk assessments are considered screening-level due to recognized uncertainties in some of the input parameters, particularly regarding oral bioavailability and potential for volatilization of the contaminants. These uncertainties were managed by intentionally overestimating these parameters to represent several conservative, high-end exposure conditions. In the case of the carpet scenario, this approach yielded a range of acceptable concentrations in the end product which vary depending on the assumed input values (see Table 2, page 7-2).

In order for this exercise to be useful, the range of acceptable concentrations must be compared to actual concentrations of contaminants in the end products. As you know, Clariant has provided these concentrations primarily based on in-house chemical analyses of the pigment products coupled with knowledge of the highest pigment usage rate in the carpet fiber application.

To confirm the end product concentration values, and at EPA's request, Clariant is obtaining congener-specific analyses of additional pigment lots using a commercial laboratory. Clariant recently received draft results of these additional tests but not in time to be considered in today's submittal. Clariant will require additional time to evaluate the results and to verify the calculated end product contaminant concentrations. Additional analytical testing also may be necessary.

Since the end product contaminant concentrations do not affect the approach and methodology of the risk assessments, please review the enclosed document and provide comments back to Clariant. All analytical data on commercial pigment lots will then be





compared to the acceptable concentrations calculated by the screening-level risk assessment to determine what, if any, additional work is required.

If you have any questions or need additional information, please feel free to contact me at 704-331-7104.

Sincerely,

**CLARIANT CORPORATION** 

Michael A. Teague, Ph.D. Vice President / ESHA

Enclosure

CC:

Erin Russell, Esq. John Schell, Ph.D.

John Paul

Robert Freet, Ph.D.

# EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR CARPET FIBER AND FOOD WRAP SCENARIOS ASSOCIATED WITH PIGMENT RED 144/214

Prepared for Clariant Corporation 4000 Monroe Road Charlotte, NC 28205

> Prepared by BBL Sciences 2940 Kerry Forest Parkway Tallahassee, Florida 32309

> > December 6, 2004



# EXPOSURE AND SCREENING-LEVEL RISK ASSESSMENT FOR CARPET FIBER AND FOOD WRAP SCENARIOS ASSOCIATED WITH PIGMENT RED 144/214

Prepared for Clariant Corporation 4000 Monroe Road Charlotte, NC 28205

> Prepared by BBL Sciences 2940 Kerry Forest Parkway Tallahassee, Florida 32309

> > December 6, 2004

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### 1. Introduction

Clariant Corporation manufactures a wide range of specialty chemicals including pigments for various industrial and household products. Two of these pigments, Pigment Red 144 and 214 have been produced at the Coventry, Rhode Island facility since about 2002. The synthesis of these di- and trichloroaniline-based pigments has the potential to inadvertently generate several congeners of polychlorinated biphenyls (referred to as total PCBs, or "tPCBs"). This has been recognized by the United States Environmental Protection Agency (USEPA) and accounted for in their rulemakings (See 48 Fed. Reg. 50846, November 1, 1983). Recently, Clariant Corporation (Coventry facility) discovered that approximately 19 commercial lots of pigment formula contained tPCB's in excess of the 50 ppm maximum permitted concentration. Although Clariant halted the production of these pigments after the discovery on September 9<sup>th</sup> 2003, certain amounts of the product were released into the stream of commerce. Clariant notified its direct customers regarding the problem and requested the return of any unused pigment material. Clariant also accepted returns of processed materials containing the pigment. Furthermore, Clariant performed several risk assessments of the pigments' impact on its manufacturing processes, as well as on some end use applications.

To assess the likelihood for exposure and risk to human receptors associated with the potential release from the non-compliant pigment, the Clariant Corporation constructed a Conceptual Exposure Model (CEM; BBL, 2004). A CEM forms the basis for identifying exposure scenarios that need to be evaluated in a risk assessment context. Developed from existing information and relevant data, a CEM characterizes all potential or suspected sources of a chemical or chemicals of concern, types and concentrations of chemicals detected in primary products, transportation and distribution of primary products to secondary users, potentially affected media, and potential exposure pathways, including potential receptors. The objective of a pigment-specific CEM is to evaluate existing product-specific data to develop an understanding of the potential nature, extent, and distribution of tPCB-containing products and to identify significant data gaps. The exposure scenarios that are identified during the development of a CEM are a function of the potentially exposed population, the quantities of the product sold, the possible routes of exposure to chemicals of concern, and the pathways by which chemicals of concern reach a human receptor.

The CEM (BBL, 2004) identified fiber/carpet yarn and food wrap as two scenarios that needed further attention in a more detailed analysis. The current screening-level risk assessment fulfills that requirement by conducting separate exposure and risk assessments for children potentially exposed to carpet fiber and for the general population potentially exposed to food wrap. The goal of this screening-level risk assessment is to calculate

risk-based levels of tPCBs in carpet yarn and fiber using cancer and non-cancer risk/hazard thresholds and children-specific exposure factors. For the food wrap scenario, a separate risk assessment is performed using information published in the Federal Register (62 Fed. Reg. 9365, March 3, 1997) and the maximum concentration of tPCBs contained in the tinted food wrap.

One concern expressed by USEPA in their review of the CEM was the potential for the release of pigment from a production facility, and subsequent exposure via fugitive dust. However, this is not considered a potential complete exposure pathway for the following reasons. First, the dyes containing Pigment Red 144 and 214 are no longer produced with concentrations of tPCBs that exceed the regulatory limit, and the large proportion of pigments not incorporated into end products have been returned to the producer. Since Clariant is not aware of any spills reported at any production facility, and the contaminated pigments are no longer produced, the potential for a "release from production activities" is extremely minute. Second, the pigments were not produced in the quantity that would result in large amounts of material to be stored or unused, thus reducing the potential for a major spill. Also, because it was a valued product, the handling of the material was such so as to limit the loss of material during the production activities. Finally, Pigment Red 144 and 214 are brightly colored powder pigments and if there had been a spill, it would not have gone unnoticed and it would have been cleaned up right away. Therefore, a "spill" would not represent a long-term exposure to workers.

Because of the unique nature of the exposure scenario, many of the parameters needed to quantify risks, or calculate risk-based concentrations, are not readily available. Due to this lack of information, certain key variables needed to be estimated using best professional judgment. This resulted in the introduction of some uncertainty. Therefore, the estimated variables were typically intentionally overestimated, and represented highend exposure conditions. Addressing uncertainty in this fashion is consistent with USEPA recommendations and guidance (USEPA, 2001). Because of the conservative approach, this assessment is reflective of the screening-level step in the human health risk assessment process. That is, many of the exposure variables were set at the high-end of the expected values, with the result of this redundant conservatism being risk-based concentrations that do not represent toxicological thresholds, but rather levels that are clearly without risks. Identification of pathways and chemical concentrations that are without significant risks is the purpose of the screening-level risk assessment.

The current screening-level risk assessment focuses on tPCBs from Pigment Red 144 and 214. From a risk perspective, total PCBs are considered as the chemicals of potential concern. In particular, because PCB congeners 44 and 70 make up about 90% of the total PCBs found in the pigments, these two congeners are used to characterize the physico-chemical properties of the tPCBs contained in the pigment.

# 2. Carpet Scenario

The primary receptors for this analysis are young children (1 to 10 yrs old), who may be exposed to tPCBs in the pigments via daily activities on carpeted surfaces. This potentially highly exposed population subgroup was chosen to reflect the conservative nature of the screening-level risk assessment. The activities assumed to lead to potential exposure consist of:

- 1. Mouthing of carpet surfaces, toys, hands and feet leading to the ingestion of the associated carpet fiber and dust;
- 2. Crawling, walking, and kneeling leading to dermal uptake via the exposed skin; and
- 3. General day-to-day indoor activities leading to the inhalation of fibers, dust, and tPCB vapors suspended in the air.

The extent of contact between children and carpet-borne constituents of interest is calculated via a deterministic exposure model. This model considers ingestion, dermal uptake, and inhalation exposure routes. The model and the associated input parameters are discussed below.

#### 2.1 Exposure Model

To calculate the acceptable concentration of tPCBs in carpet, adopting child-specific exposure parameters and USEPA-promulgated, PCB-specific, non-cancer reference doses and cancer risk slope factors, an algorithm based on USEPAs (2002) guidance was modified to assess the carpet fiber exposure scenario.

#### 2.1.1 Non-Cancer Hazard

The combined exposures calculation model for non-cancer hazard is as follows:

$$CNC_{Curper} = \frac{THQ \cdot BW \cdot AT_{nc}}{ED \cdot EF \left[ \left( \frac{1}{RfD} \cdot \frac{IR \cdot BioAF}{10^6 \, mg/\, kg} \right) + \left( \frac{1}{RfD} \cdot \frac{SA \cdot AF \cdot DERM}{10^6 \, mg/\, kg} \right) + \left( \frac{1}{RfD} \cdot IHR \cdot C_g \cdot VRF \right) \right]}$$
Equation 1

where,

CNC<sub>Carpet</sub>-risk-based concentration in carpet fiber associated with hazard quotient of 1 (mg/kg),

THQ-target hazard quotient (unitless),

BW-body weight (kg)

RfD-non-cancer reference dose (mg/kg BW/day),

 $AT_{nc}$ -non-cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm²/day),

AF-dust adherence factor (mg/cm2),

DERM-dermal absorption factor (unitless),

IHR-inhalation rate (m3/day),

 $C_g$ -room air concentration of tPCB vapor (mg/m<sup>3</sup>), and

VRF-volatilization rate factor (unitless).

Concentration in air  $(C_g)$  used in the above equation was calculated via a set of concentration relationships derived experimentally for an enclosed chamber containing carpet sample impregnated with a substance of interest (Bennet and Furtaw, 2004 citing Won et al., 2000). The relationships describing carpet surface to air partitioning  $(K_{Sd})$  are as follows:

$$K_{SA} = \frac{\frac{k_s}{k_d}}{d_w} = 10^{3.82 - 0.62 \log VP}$$
 Equation 2

where,

$$\frac{k_s}{k_d} = \frac{M}{C_g}$$
 Equation 3

substituting Equation 3 into Equation 2 and solving for  $C_g$  yields,

$$C_g = (\frac{d_w \cdot 10^{3.83 - 0.62 \log VP}}{M})/D$$

**Equation 4** 

where,

 $k_s$ -adsorption coefficient (m/hr),

 $k_d$ -desorption coefficient (m/hr),

 $d_w$ -carpet thickness (m),

VP-vapor pressure (Pa),

M-carpet area mass (mg/m2), and

D-number of room air exchanges after one week.

Calculations were repeated for bioavailability factors of 0.01, 0.05, 0.1, 0.5, and 1 and for volatilization rate factors of 0.001, 0.005, and 0.01. The reason for handling these parameters as variables is described in the Uncertainty Section of this report (Section 4). The input variable parameterization is summarized in Section 2.2 as well as Table 1.

#### 2.1.2 Cancer Risk

The combined exposures back-calculation model for cancer risk is as follows:

$$CC_{Curpet} = \frac{TR \cdot BW \cdot AT_{c}}{ED \cdot EF \left[ \left( \frac{CSF \cdot IR \cdot BioAF}{10^{6} mg/kg} \right) + \left( \frac{CSF \cdot SA \cdot AF \cdot DERM}{10^{6} mg/kg} \right) + \left( CSF \cdot IHR \cdot C_{g} \cdot VRF \right) \right]}$$

Equation 5

where,

```
CC<sub>Carpet</sub>-risk-based concentration in carpet associated with 1 x 10<sup>-6</sup> cancer risk (mg/kg),
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TR-Target cancer risk,

BW-body weight (kg)

CSF-Cancer slope factor (mg/kg BW/day)<sup>-1</sup>,

 $AT_c$ -cancer averaging time (days),

ED-exposure duration (yrs),

EF-exposure frequency (days/yr),

IR-dust ingestion rate (mg/day),

BioAF-bioavailability factor for ingestion (unitless),

SA-contact skin surface area (cm<sup>2</sup>/day),

AF-dust adherence factor (mg/cm²),

IHR-inhalation rate (m³/day),

DERM-dermal uptake factor (unitless),

 $C_{\rm g}$ -room air concentration of tPCB vapor (mg/m<sup>3</sup>), and

VRF-volatilization rate factor (unitless).

Calculations for cancer risk were also repeated for bioavailability factors of 0.01, 0.05, 0.1, 0.5, and 1 as well as for volatilization rate factors of 0.001, 0.005, and 0.01.

#### 2.2 Model Parameterization

The exposure parameters, models, concentration data, risk factors, and assumptions used in the current assessment were obtained from a number of sources including the USEPA guidance documents, published literature, the internet, and Clariant's database. Input parameters are summarized in Table 1. The paragraphs below discuss each input parameter in detail.

#### 2.2.1 Body Weight

The receptor of interest in the carpet scenario is a young child that is expected to be in direct contact with carpeted surfaces as a result of normal daily activities such as playing, walking, and crawling. The range of age within this group can conceivably span from 1 to 10 years. The calculated average body weight for children of that age is 21.8 kg (USEPA, 2000; Table 1).

#### 2.2.2 Temporal Parameters

The time scale of the exposure and risk estimate is set to coincide with the useful life span of a residential carpet. According to an industry source, carpet warranties may span from 5 to 20 years. However, a typical carpet lasts about 10 years (Bigger and Bigger, 2004). Therefore, the exposure duration in this assessment was assumed to be 10 years. This is equivalent to the 3650 days used as the averaging time in non-cancer hazard calculations. For the cancer risk assessment, a default life expectancy of 70 years was used to derive the lifetime average daily dose (25,550 days; USEPA 1997, 2002) (Table 1). The exposure frequency was set to the default of 350 days per year (USEPA 1997, 2002) and the event frequency at one event per day.

#### 2.2.3 Ingestion Parameters

The primary mode of tPCB intake in this exposure scenario is assumed to be via the incidental ingestion of carpet fibers/dust as a result of mouthing of carpet surfaces, toys, hands, and feet. Because no ingestion rate data for the carpet fiber were readily available in the published literature, a conservative assumption was made that the carpet fiber intake by children is comparable to that of soil dust. According to data from Moya et al. (2004), children consume an average of 55 mg of soil dust per day. That value was used to approximate the daily fiber ingestion rate (Table 1). This is a conservative assumption because unlike loose soil particles, carpet fibers are not easily displaced, since they are designed specifically to hold fast to the carpet backing.

A bioavailability factor was introduced into this component of the exposure/risk model to account for the proportion of the tPCBs in carpet that may be dislodged via the digestive tract activities. This factor was set to range from 1 to 100% (Table 1) due to the uncertainty as to its real empirical magnitude. At this time, the bioavailability factor remains a data gap and it is viewed as a crucial component of the overall risk assessment.

Recent studies suggest that the bioavailability of lipophilic compounds like tPCBs and dioxins are reduced when adsorbed to the soil matrix. Ruby et al. (2002) reported that the bioaccessibility (a surrogate for oral bioavailability) of low concentrations of PCDDs and PCDFs ranged from 19 to 34%. Similar results were reported by Hack and Selenka (1996) for PCBs in a "standardized gastro-intestinal model." Although carpet fibers may differ in important physical parameters affecting intestinal absorption from soil, most significantly, the tPCBs in the pigment are permanently encapsulated in the polymer shell of the fiber during the coloring process and they are unlikely to be as easily mobilized off the fiber as they are in the soil matrix. Therefore, even the assumption of 1% "bioavailability" likely overestimates the fraction of tPCBs available for absorption.

#### 2.2.4 Inhalation Parameters

The inhalation rate of the receptor was set at 10.4 m<sup>3</sup>/day, which is the average estimate for children ranging from 1 to 10 yrs old (USEPA, 2000) (Table 1). Although PCBs are large molecules and have only limited volatility at room temperature, an assumption was made that some amount may enter the room air and be available to be inhaled. The tPCB vapor contribution to the overall exposure burden was estimated via a set of empirical models derived from air chamber experiments (Equations 2 to 4; Bennet and Furtaw, 2004). The required parameters in these models include carpet thickness, carpet area mass (also called face weight), and vapor pressure. Average carpet thickness was set to 0.0129 m and face weight to 1,700,000 mg/m<sup>2</sup> based on information obtained from the carpet industry (Table 1; RPA, 2004; Carpet USA, 2004). The vapor pressure parameter was set to 0.0069 Pa and consisted of a mean of all values for PCB congeners 44 and 70 reported in the compendium by MacKay et al. (1992) (Table 1). To account for dilution due to ventilation, the air concentration estimated by Equation 4 was divided by the average number of air exchanges in a residential dwelling over one week. According to Murray and Burnmaster (1995), a house receives, on average, 18 air exchanges per day. This is equivalent to 126 exchanges per week. The application of this factor to the calculated air concentration yields a maximum room air concentration of 0.000009 mg tPCB/m<sup>3</sup> (Table 1). This estimate is very conservative because the current calculations implicitly assume that the tPCB load will be renewed (i.e., an inexhaustible source) in the carpet every seven days over the carpet's life span of 10 years. Clearly, the estimated air concentration is much higher than what would be measured in an actual house with far more frequent ventilation rates and no possibility of tPCB replenishment.

The inhalation of tPCB-laden house dust containing carpet fibers was not explicitly accounted for in the exposure/risk models because initial calculations revealed that the relative contribution of tPCBs entering the receptor via this exposure route is exceedingly small even under the most conservative exposure assumptions. For example, assuming that 100% of the house dust consists of carpet fibers and that all of the tPCB fiber residue is available for uptake, the maximum concentration of tPCB available for uptake is 3.8 mg/kg dust (maximum concentration of tPCBs measured in carpet fiber; BBL, 2004). Long et al. (2000) reported that an average concentration of dust in a non-smoker's house is 3.6 µg/m³. Multiplying that number by the daily inhalation rate of a child (10.4 m³/day; Table 1) yields a daily dust inhalation rate of 37.4 µg dust/day or 3.7 x 10<sup>-8</sup> kg dust/day. Since the dust is assumed to contain 3.8 mg tPCBs/kg, the daily tPCB intake is 1.4 x 10<sup>-7</sup> mg/day. Normalizing to the body weight of 21.8 kg (Table 1) yields an intake rate of 6.4 x 10<sup>-9</sup> mg tPCB/kg BW/day. This value is nearly four orders of magnitude below the non-cancer and cancer hazard thresholds. Clearly, the relative contribution of house dust to the inhalation exposure route (and hazard/risk) is exceedingly small and consequently does not warrant explicit consideration in the exposure/risk model.

#### 2.2.5 Dermal Uptake Parameters

Young children may spend much of their time crawling, walking, and kneeling. In an indoor environment, this may translate into dermal uptake via the exposed skin on knees, elbows, hands, and feet. According to USEPA (2000), the skin surface area available for contact during warm-weather play, with 32% of the total skin surface area exposed, is 2,763 cm²/day (Table 1). The adherence factor, or the amount of material remaining on the skin after contact is estimated at 0.00724 mg/cm² (USEPA, 2000). This value reflects soil adherence for children, post-activity, indoors, and on hands, arms, legs, and feet. Again, an assumption is made that carpet fibers behave similarly to soil particles. This represents an uncertainty in the assessment.

The USEPA's default value for the dermal absorption factor for tPCBs in soil of 14 % (USEPA, 2001) was adopted as the default value in this screening-level risk assessment. A recent report by Mayes et al. (2002) demonstrated that the dermal absorption of tPCBs from soil may be lower, approximating only 4% of the applied dose. Although carpet fibers may differ in important physical parameters affecting dermal absorption from soil, manufacturing processes also impact the amount of tPCBs available for absorption. The tPCBs in the pigment are permanently encapsulated in the polymer shell of the fiber during the coloring process and are unlikely to be as easily mobilized off the fiber as they are in the soil matrix. Thus, use of the default dermal absorption factor is likely an overestimate. Although there are no empirical data to quantify the amount of tPCBs that might be liberated from the carpet fiber, anecdotal evidence indicates this is unlikely to be a significant amount. Individuals in contact with carpet, even young children crawling on the material, never show evidence of color transfer. In the case of these pigments, children, for example, do not exhibit red knees, which would be evidence of a direct and substantial transfer of the encapsulated pigments (and tPCBs) onto the skin. As such, assuming a dermal absorption of 14% of the applied tPCBs from carpet substantially overestimates the exposure from this pathway.

#### 2.3 Hazard and Risk Reference Values

Because no toxicity reference information for PCB 44 or 70 was available, Aroclor 1254 reference dose was used as a surrogate. This is a very conservative step because an Aroclor mixture usually contains congeners that are assumed to be more persistent and potent than PCB 44 or 70. This further increases the degree of conservatism in the current assessment. The non-cancer reference dose for Aroclor 1254 is 0.00002 mg/kg/day (USEPA, 2002). The cancer slope factor of 0.07 (mg/kg/day)<sup>-1</sup> represents the lowest risk and persistence category recommended by the USEPA (2002). The target risk used in the calculation was the low end of USEPA's "acceptable risk range" of 1 in one million of exposed individuals (1 x 10<sup>-6</sup>) (USEPA, 1996; 1997; 2000) (Table 1). The target hazard quotient was set to one (1).

#### 2.4 Results and Discussion

According to the exposure/hazard model for non-cancer effects, the combined ingestion, inhalation, and dermal uptake may lead to allowable concentrations in carpet fiber ranging from approximately 8 to 132 mg tPCBs/kg depending on the magnitude of the bioavailability and volatilization rate factors (Table 2; Figure 1). In contrast, the acceptable concentrations of tPCBs in carpet fiber associated with a 1 in a million cancer risk are much higher and range from approximately 39 to 660 mg/kg (Table 2; Figure 2). Comparing the tPCB concentrations reported in the finished product (carpet), which reached a maximum of 3.8 mg/kg in one carpet brand, to the results from the current assessments suggests that even at 100% bioavailability and 1% volatilization rate, it is highly unlikely that any cancer or non-cancer risk/hazard responses will be triggered. This observation is made despite the excessive amount of conservatism built into the current screening-level risk assessment. Because many of the critical physical/chemical parameters dictating how pigments (and tPCBs) behave in carpet fiber, are unknown this uncertainty was accounted for by intentionally overestimating many of these important factors. Rather than viewing these results as accurate predictors of risk, the important fact is that even applying these high-end assumptions, the levels of tPCBs measured in the red pigments represent little or no unacceptable risk.

# 3. Food Wrap Scenario

The second exposure scenario identified by the CEM as requiring a detailed analysis is the scenario where a polymer film is used as a food contact material. This exposure scenario is based on a dual layer wrap product, in which, the tinted outer non-food contact layer of the wrap contains the affected pigment. The analysis of this scenario focuses on emulating the FDA assessment published in the Federal Register Notice for a pigment colorant in polymers intended for use in contact with food.

#### 3.1 Federal Register Notice

The Food and Drug Administration (FDA) evaluated the safety of Pigment Red 254 used as a colorant in polymers intended as packaging material for food (62 Fed. Reg. 9365, March 3, 1997; Notice). Pigment Red 254 could contain inadvertently generated PCBs as permitted under applicable regulations. The FDA concluded that there is a reasonable certainty that no harm from exposure to tPCBs would result from the proposed use of the pigment in food packaging. The agency stated that it would not expect that the inadvertent impurity (tPCBs) would become a component of food at other than extremely low levels. The conclusion of no risk was based on the upper-bound calculated human cancer risk of less than 7.5 x 10<sup>-13</sup>. The actual lifetime-averaged individual exposure (and risk) to tPCBs is likely to be substantially less because very conservative assumptions were used to set the worst-case scenario employed by FDA.

#### 3.2 Pigment Red 144/214 in Cheese Wrap

We expect that the PCB contaminants in Pigments Red 254 and 144/214 behave in a similar fashion, and it is very plausible that the methodology used by FDA is applicable for both pigments. We repeat the risk analysis for Pigment Red 144 and 214 to capture the case-specific concentration of 1.1 mg tPCBs/kg in the film used to wrap cheese (BBL, 2004). The cheese food category encompasses cheeses such as blue, brick, camembert, brie, cheddar, gouda, edam, limburger, mozzarella, parmesan, Swiss, cream, and processed. Exposure parameters relevant to that food group were obtained from Smiciklas-Wright et al. (2002).

In the current assessment, a conservative assumption was made that the entire residue of tPCBs contained in the outer layer of the film will transfer through the inner layer to the food item instantly. Thus, assuming that each square inch of film contacts ten grams of food (FDA's standard assumption) and that the film face weight is 0.035 g/in<sup>2</sup> (Clariant, undated), the maximum concentration of tPCBs in the contacted food (cheese) is 0.00385

mg/kg cheese<sup>1</sup>. The actual amount and rate of the tPCB transfer are likely much lower because the pigment is contained in the separate outer layer, which is not in the immediate contact with food. Also, it would be expected that under refrigerated conditions migration should occur only at a slow rate, if at all. Thus, it is probable that the pigment never becomes incorporated into the food material.

To estimate the tPCB exposure of a person eating cheese, the calculated tPCB concentration must be multiplied by the amount of cheese consumed by a typical consumer. According to Smiciklas-Wright et al. (2002), average consumption of cheese is 0.026 kg per person per day. Given the average body weight of an adult of 70 kg, the exposure rate to tPCBs is 0.0000014<sup>2</sup> mg tPCBs/kg BW/day.

#### 3.3 Results and Discussion

Comparing the calculated exposure to the non-cancer hazard threshold of 0.00002 tPCBs mg/kg BW/day (Table 1) reveals that the worst-case cheese exposure is about 15-fold lower than the trigger associated with non-cancer effects. In terms of the cancer threshold (0.00001429 mg tPCB/kg BW/day; Table 1), the estimated exposure resulting from cheese consumption is about 10 times lower than that needed to exceed the cancer level risk of 1 in 1,000,000.

This analysis shows that the potential exposure to tPCBs resulting from eating cheese wrapped in red film is very low and highly unlikely to result in any toxicological responses in the population at large.

 $<sup>^{1}</sup>$  1.1 mg tPCBs/kg film x 0.000035 kg film /in<sup>2</sup> film x 1 in<sup>2</sup> /0.01 kg food (cheese) = 0.00385 mg tPCB/kg food (cheese)  $^{2}$  0.00385 mg tPCBs/ kg cheese x 0.026 kg cheese/person/day x person/70 kg = 0.0000014 mg tPCBs/ kg BW/day

# 4. Uncertainty

Because of the methodology required to estimate exposure and toxicity, uncertainty is inherent in the risk assessment process. Uncertainty in this context is attributed to either a lack of knowledge (referred to as "incertitude") or natural variability. Incertitude can be addressed by collecting additional information (i.e., obtaining additional site-related data), while uncertainty attributable to natural variability cannot be easily reduced.

The performance of the quantitative assessment, and the development of risk-based tPCB concentrations associated with the exposure pathways identified as "complete" in the CEM, have a number of uncertainties. These uncertainties fall primarily in the category of incertitude and are attributable to a lack of knowledge or information. While some of the parameters used to characterize exposure were obtained from USEPA guidance documents or the published literature, many important inputs were based on best professional judgment. Similarly, not only were characterization variables estimated, but some of the more basic information, such as the actual concentration of tPCBs in a home carpet, was estimated or based on internal calculations. While this estimate was based on limited empirical data, the concentration in the carpet actually contacted by the hypothetical receptor was assumed to be reflective of a carpet containing 100% red pigment (Pigment Red 144 and/or 214). While no surveys were conducted to bound the uncertainty associated with this assumption, we cannot confirm that bright red carpet is actually used in a household setting. To the contrary, industry representatives indicate that red pigment would generally not be used as the sole colorant in household carpets. Making the assumptions that an individual was exposed only to bright red carpet, and that the carpet was composed entirely of fibers with Pigment Red 144/214, overestimates the exposure to tPCBs and, therefore, the risks and hazards associated with this pathway. The magnitude of this overestimation cannot be quantified at this time, but it is undoubtedly substantial, perhaps ranging over several orders of magnitude. Indeed, if fibers containing Pigment Red 144 or 214 comprise only ten percent (10%) of the carpets that were actually manufactured, the risk-based concentrations presented in Table 2 would increase by an order of magnitude.

Additionally, if the carpets that were actually manufactured using Pigment Red 144 and/or 214 were not used in residential settings, (as assumed in this screening-level risk assessment) but rather in industrial settings, then the risk-based concentrations in Table 2 would increase as well. Non-residential uses eliminate young children as receptors of concern thereby eliminating two high-end pathways of exposure – direct dermal contact with carpet and ingestion of tPCB as a result of mouthing behavior.

Because of the unique nature of the hypothetical situation evaluated in the assessment, standard default values had to be modified and adapted to the conditions assumed in the scenario. While data characterizing the "carpet scenario" are not specified in any USEPA guidance document, certain assumptions were made based on best professional judgment. For example, it was assumed that the primary exposure pathways were ingestion of liberated fibers, dermal contact with the fibers in the carpet, and inhalation of tPCB vapors emanating from the carpet fiber. Due to the manufacturing processes, in reality, the exposure pathways are likely to be insignificant. In producing colored carpets, the pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. This encapsulation process effectively reduces the potential for the pigment mobilizing off the fiber material. During the early phase of this project, Clariant determined that tPCBs could be effectively extracted from a polymer matrix only with a non-polar solvent such as hexane, and that using water for such extractions yielded no detectible levels of tPCBs. Therefore, the assumption that a significant amount of the pigment (and associated tPCBs) are released from the fiber and are free to be absorbed in the gastrointestinal tract, enter the skin, or volatilize into the surrounding air to be inhaled, are not based on any empirical data, but rather represent a worst case exposure scenario.

Addressing uncertainty by overestimating certain parameters is a standard technique in the USEPA-promulgated process. However, making these assumptions in order to complete the assessment does not suggest that Clariant endorses, or has information to support these exposure parameters. In fact, observational data suggests that pigments (and associated tPCBs) are not readily transferred directly from the fiber or the skin as individuals routinely in contact with carpet do not show obvious signs (i.e., color) on their skin or clothes. Likewise, significant transfer of pigment off the fiber would result in obvious fading over a relatively short period of time. Again, this is not routinely observed. Therefore, this direct transfer of tPCBs would not occur in quantities that might represent significant exposure (on the skin and ingested via hand-to-mouth activity). Therefore, this direct transfer of tPCBs would not occur in quantities that might represent significant exposure (on the skin and ingested via hand-to-mouth activity).

Similarly, the volatilization factors used in the inhalation exposure model were based on best professional judgment since no empirical data are available. The assumed volatilization rates of 0.1% to 1% were based on consideration of the manufacturing and end-use conditions. As previously noted, during the production of colored carpets, the pigment is permanently encapsulated in the polymer shell of the fiber during the coloring process. This process would dramatically reduce any potential for PCB molecules to volatilize off the fiber. Also, explicit in the model used to estimate air concentration, the amount of PCBs in the fiber represents an infinite, inexhaustible source (i.e., the concentration term stays constant). Use of higher, physically unlikely,

volatilization factors would require that tPCBs be replenished since volatilization rates of 10% or higher over a 10-year period would substantially reduce the source in the fiber. Assuming these higher volatilization rates would require the development of a first-order decay function for use in the exposure model, this decay factor and higher volatilization rates would result in depleted tPCB concentrations in the fiber and, therefore, much lower air concentrations over time than what was assumed in the current assessment.

There are also experimental data to support the use of these low volatilization rates. Qi (2003) reported that on average, 5% of pure PCBs, placed on glass volatilized into the air. Since this volatilization occurred under favorable conditions, it is considered a high end estimate. Because of the manufacturing process of encapsulating the pigment in the polymer shell of the fiber, this upper estimate is not particularly relevant to the carpet exposure scenario, although, it does provide a support for the selection of the volatilization rates used in the screening level assessment.

One acknowledged data gap is associated with the above discussion. Because the colorization/encapsulation process is unique, there are no available data that can be directly extrapolated to the exposure scenario. Thus, perhaps the greatest source of uncertainty, in terms of impacting the estimate of an internal dose of tPCBs, is the amount of tPCBs liberated from the fiber that can be absorbed across biological membranes. Because of this uncertainty, the screening-level risk assessment used a range of bioavailability and volatilization factors to estimate exposure. Based on manufacturing processes and observational data that illustrate that the pigments are tightly bound to the fibers, assumptions above even 10% are significantly overestimating exposure and therefore risk. However, additional data would be required to quantify the magnitude of this overestimation.

Other uncertainties that were addressed by conservative estimates include the assumption that fiber particles behave like soil in terms of estimating dermal exposures. Adherence factors in particular, are likely overestimating the time and the amount that the fiber is in direct contact with the skin. Similarly, in a house that is kept clean and vacuumed, the contribution of carpet fiber to the house dust would be minimal. Thus, the assumption of an ingestion rate of 55 mg/day is not based on any scenario-specific information, but rather is based on estimates from studies on children playing outdoors. Again, adopting this exposure factor likely overestimated dust ingestion.

## 5. Conclusions

The purpose of this screening-level risk assessment was to satisfy a request from the USEPA to provide a bounding estimate on the hypothetical risks and hazards that might have been associated with one-time, past use of red pigments produced by Clariant that were subsequently found to contain trace concentrations of tPCBs above the allowable level. These contaminated pigments are no longer produced or sold by the Clariant Corporation and are no longer being inserted into commerce where they could potentially be contacted by the public. However, in order to attempt to place into context the upper bound estimate of theoretical risks associated with these past uses, risk-based concentrations associated with two scenarios with a potential for exposure to sensitive human receptors were developed. As noted in the Uncertainty section, data specific to the exposure pathways analyzed in this report are limited. In attempt to account for this limited information, and to ensure that any potential risks associated with the use of Pigment Red 144 and 214 in consumer products were addressed, theoretical exposures were intentionally overestimated. Even under these high-end exposure assumptions, the concentrations determined to be within USEPA's acceptable risks range were well above the maximum concentration of tPCBs detected in the pigmented products. The current analysis, despite the use of intentional overestimates of exposure, indicates that there was no unacceptable risk, and that there are no obvious public health concerns.

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# **Tables**



# 7. Tables

Table 1. Exposure/ Risk Model Input Parameters

Parameter	Value	Source
General	<del></del>	,1
Exposed Population: Young Children (yrs)	1 to 10	USEPA (2000)
Body Weight (1 to 12 yrs old; kg)	21.8	USEPA (2000)
Carpet Life Span (yrs)	10	Bigger and Bigger (2004)
Exposure Duration (yrs)	10	Equal to Carpet Life
Exposure Frequency (days/year)	350	USEPA (1997; 2002)
Life Expectancy (yrs)	70	USEPA (1997; 2002)
Averaging time: non-cancer (days)	3,650	USEPA (1997; 2002)
Averaging time: cancer (days)	25,550	USEPA (1997; 2002)
Ingestion		
Dust (soil) ingestion rate (children; mg dust/ day)	55	Moya et al. (2004)
Bioavailability of PCBs in Fiber (ingestion and inhalation; %)	1, 5, 10, 50, and 100	Assumption
Inhalation		
Inhalation rate (1 to 10 yrs old; m³/day)	10.4	USEPA (2000)
Complete air exchange rate (1/week; based on 18 exchanges/day)	126	Murray and Burnmaster (1995)
Air concentration in an enclosed space 7 days post-installation of a new carpet (mg/m³)	0.000009	Calculated
Vapor pressure of PCB44/70 mixture (Pa)	0.0069	MacKay et al. (1992)
Carpet thickness (m)	0.01286	RPA (2004)
Carpet area mass (face weight; mg/m²)	1700000	Carpet USA (2004)
Volatilization retention factor (unitless)	0.001 to 0.1	Assumption
Dermal		
Dust adherence factor for children post-activity indoors on hands, arms, legs, feet (mg/cm²)	0.00724	USEPA (2000)
Contact skin surface area during warm-weather play with 32% skin exposed (cm <sup>2</sup> /day)	2,763	USEPA (2000)
Dermal uptake factor	0.14	USEPA (2001)
Hazard and Risk Reference Values		
Target hazard quotient	1	USEPA (1997; 2002)
Non-cancer reference dose (mg/kg BW/day)	0.00002	USEPA (2002)
Cancer slope (mg/kg BW/day)-1	0.07	USEPA (2002)
Target cancer risk	1 x 10 <sup>-6</sup>	USEPA (1997; 2002)
Target lifetime average daily dose (mg/kg BW/day)	0.000014	equal to acceptable risk over cancer slope

Table 2. Risk-Based Concentrations (mg/kg) of tPCBs in Carpet Fiber

Oral Bioavailability	Acceptable Concentration in Carpet Fiber (mg tPCB/kg)				
Factor	Volatilization Retention Factor				
	0.001	0.005	0.01		
	Non-Can	cer Hazard			
0.01	132	119	106		
0.05	81	76	70		
0.10	54	52	49		
0.50	15	15	15		
1.00	7.9	7.8	7.7		
	Cance	er Risk			
0.01	660	596	532		
0.05	403	378	351		
0.10	271	259	246		
0.50	75	74	73		
1.00	39	39	39		

# **Figures**



# 8. Figures

Figure 1. Risk-Based Concentrations of tPCBs in Carpet Fiber for the Non-Cancer Exposure Scenario Given Bioavailability and Volatilization Rate Factors (VRF)

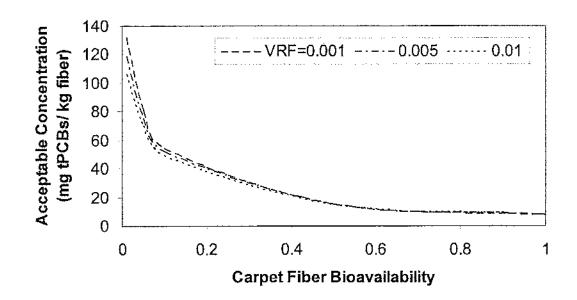
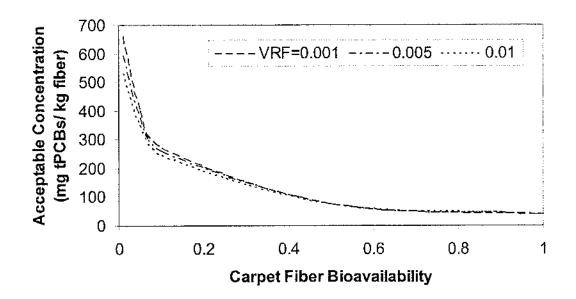


Figure 2. Risk-Based Concentrations of tPCBs in Carpet Fiber for the Cancer Exposure Scenario at Given Bioavailability and Volatilization Rate Factors (VRF)





4000 Monroe Road Charlotte, NC 28205 Environmental, Safety & Health Affairs Phone: 704–331-7206

Fax: .704-331-7105

# Eelefax

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* Date: Ea: Company: Fax No: From: No. of pages (Brilliding Cover Sheet): \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* Message: Of you do not receive the entire fax, please notify 704-331-7206. Thank you and have a nice day!



Clariant Corporation

4000 Monroe Road Charlotte, NC 28205 704,331,7000

Via FedEx

December 15, 2004

VERSAR, Inc. Attn: Didi Sinkowski 6850 Versar Center Springfield, VA 22151

RE: Red Pigment Project

Exposure and Screening-Level Risk Assessments

Dear Ms. Sinkowski:

Per the instruction of Kim Tisa, U.S. EPA Region 1, Clariant herewith submits directly to Versar the document titled "Exposure and Screening-Level Risk Assessment for Carpet Fiber and Food Wrap Scenarios Associated with Pigment Red 144/214, December 2004" prepared for Clariant by BBL Sciences:

Also enclosed is a copy of the cover letter originally submitted to Ms. Tisa on December 8 explaining the status of the risk assessment and the need for additional work regarding the analysis of contaminant levels in end products.

Sincerely,

**CLARIANT CORPORATION** 

Michael A. Teague, Ph.D. Vice President / ESHA

Enclosure

cc: Kim Tiśa (via fax) w/o enclosure